

FROMMER LAWRENCE & HAUG LLP

745 Fifth Avenue
New York, New York 10151
Telephone: (212) 588-0800
Facsimile: (212) 588-0500
E-mail: Firm@flhlaw.com

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To: Examiner Sharon T. Turner
Firm: U.S. Patent and Trademark Office
Facsimile: 703-308-4242
From: Christian Smolizza
Date: December 15, 2003
Re: Response to Restriction Requirement
USSN Serial No. 10/080,101
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Applicant(s) : NIELSEN et al.
Serial No. : 10/080,101
Filed : February 19, 2002
For : SYNTHETIC VACCINE AGENTS
Examiner : Sharon L. Turner
Art Unit : 1647

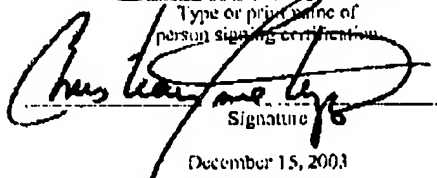
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RESPONSE TO RESTRICTION REQUIREMENT

Mail Stop Non-Fee Amendment
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Dear Sir:

In response to the Office Action mailed November 13, 2003 setting a one-month period for reply and containing a restriction requirement, Applicants elect, with traverse, Group I, claims 1-25. Applicants also elect, with traverse, the species "a bond cleavable by a peptidase". Further, Applicants elect dextran for search purposes. It is believed that no fees are occasioned by entry of this paper. However, the Commissioner is hereby authorized to charge any additional fees, or credit any overpayment in fees, to Deposit Account 50-0320.

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REMARKS

Reconsideration and withdrawal of the requirement for restriction are respectfully requested in view of the remarks herein.

The November 13, 2003 Office Action required an election under 35 U.S.C. § 121 from among the following:

- Group I:** Claims 1-25 in part drawn to an immunogen, classified for example in class 536, subclass 23.1; and
- Group II:** Claims 26-38 in part drawn to a method for immunizing an animal, classified for example in class 536, subclass 23.1.

The November 13, 2003 Office Action identifies generic claims 1 and 26, and requires an election of species from "Mechanisms of coupling selected from a) a bond cleavable by a peptidase, b) an amide bond, c) a peptide bond, d) polyhydroxypolymer carriers . . ." (Office Action at 3).

The claims of Group I are elected, with traverse, for further prosecution in this application. Applicants reserve the right to file divisional applications to non-elected subject matter.

Applicants also provisionally elect, with traverse, the species "a bond cleavable by a peptidase". Further, Applicants elect dextran for search purposes. This election is also made with traverse as the species are each related to one another and directed to the same inventive concept, i.e., capable of being simultaneously searched. It is Applicants' understanding that upon the allowance of a generic claim, Applicants will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all of the limitations of an allowed generic claim as provided by 37 C.F.R. 1.141.

Favorable reconsideration and withdrawal of the requirement for restriction from among Groups I and II are respectfully requested. Applicants respectfully traverse the restriction and election requirements. The present invention relates to the fields of immunology and vaccine technology. The present claims, therefore, represent a web of knowledge and continuity of effort that merit examination in a single application. Indeed, the claims of both Groups are related since the claims of Group I are directed to an immunogen and the claims of Group II are directed to a method of immunizing an animal. The aforementioned immunogen is included in the method claims of Group II. It is respectfully pointed out that the Examiner, in defining the subject

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matter of Group II, failed to recognize that the methods of Group II are dependent, directly or indirectly, on claim 1, *i.e.*, the methods of Group II comprise the limitations of claim 1.

It is respectfully submitted that the claims in Groups I and II may be searched and examined together without serious burden. For example, the claims of Group II are directed to a method containing the elements of Group I, and is dependent, directly or indirectly, on claim 1. Thus, a search of the claims of Group I would necessarily include a search of the claims of Group II.

The Examiner's requirement for restriction for Groups I and II was made pursuant to the provisions of M.P.E.P. §806.05(h). It is alleged by the Examiner that the inventions are patentably distinct from each other because, "In the instant case the processes for using the immunogens can be practiced with alternative immunogens and the products as claimed can be used alternatively in a method of treatment, a method of making antibodies, a method of screening compounds, and a method for detecting compositions. " (Office Action at 2).

It is respectfully submitted that the criteria necessary for classifying Groups I and II as distinct inventions has not necessarily been met.

Thus, contrary to the above views expressed by the Examiner, it is highly unlikely that the method claims of Group II can be practiced with another materially different product or the product claims of Group I can be used in a materially different process. The claims of Group II are dependent, directly or indirectly, on claim 1, and as such, contain all the limitations of claim 1; thus, the Group II method claims cannot be practiced with a "materially different product."

Even if the immunogens of Group I can be used in a materially different process, as suggested in the Office Action, the immunogens used in Group II are directly related to the claims of Group I and a search of the claims of Group I would necessarily include a search of the claims of Group II. Thus, it is respectfully asserted that the claims of Groups I and II should be joined together, since the Group I search would encompass a search and examination of Group II.

Further, it is respectfully asserted that the claims of Groups I and II are related to the same inventive concept. One of skill in the art would appreciate that the immunogens of Group I may be used to practice the claims of Group II. Furthermore, the claims of Groups I and II are classified in class 536, subclass 23.1, further demonstrating the relationships between the Groups.

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Therefore, it is maintained that a search of the invention of Group I would substantially overlap with the searches for the claims of Group II and would not present an undue burden. Thus, restriction is not appropriate. It is believed that a proper search to determine the patentability of claims 1-25 of Group I would include the methods, as defined in the claims of Group II. Applicant kindly refers the Examiner to a provision of the MPEP §803, which provides that, even if restriction is proper:

If the search and examination of an entire application can be made without serious burden, the examiner must examine it on the merits, even though it includes claims to distinct or independent inventions.

In the present case, it is courteously submitted that a search and examination of the claims in Groups I and II can be made without serious burden. Simply, searching and examining the claims of Group I would consequently and inextricably encompass searching and examining the claims included in Group II.

Moreover, it is respectfully submitted that the Examiner has not made the requisite showing of serious burden as to Groups I and II, such that restriction of the claims among Groups I and II, it is respectfully submitted, is improper.

The Examiner will have to study Applicant's entire application in connection with the examination of the elected invention. No additional effort will be required to study the application with respect to the claims of Group II.

It is respectfully submitted that Groups I and II designated by the Examiner do not warrant separate examination and search. Accordingly, the restriction requirement should be reconsidered and withdrawn, especially given that the requisite showing of serious burden has not been made. Therefore, it is respectfully submitted that, Groups I and II be rejoined.

With regard to the election of species requirement, it is respectfully requested that the requirement for species election be reconsidered and withdrawn and, in this regard, the Examiner is respectfully requested to review M.P.E.P. § 808.01(a) which states that "where there is no disclosure of relationship between species (*see* M.P.E.P. §806.04 (b)), they are independent inventions and election of one invention" is required (July 1998). In view of M.P.E.P. § 803, however, when the generic claim includes sufficiently few species that a search and examination of all the species at one time would not impose a serious burden on the examiner, then a

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requirement for election is inappropriate. Here, the species are not too great in number and can be searched without serious burden. Therefore, the request for species election should be reconsidered and withdrawn.

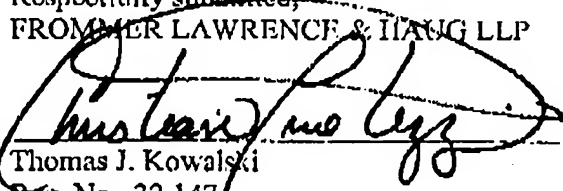
It is also respectfully urged that restricting the claims in the manner suggested in the election of species requirement constitutes an undue burden to the Applicants. If followed, the election of species requirement would require Applicants to file a number of additional applications. The cost of prosecuting and maintaining additional patents is unreasonable in view of the fact that the application as filed includes claims that are all related to one another. Further, under GATT, the period of exclusivity for any patents that issue from these divisional applications is greatly reduced.

CONCLUSION

Accordingly, in view of the foregoing, reconsideration and withdrawal of the requirements for restriction and for election of species is respectfully requested, and an early action on the merits is also earnestly solicited.

Respectfully submitted,
FROMMER LAWRENCE & HANG LLP

By:



Thomas J. Kowalski
Reg. No. 32,147
Christian Smolizza
Reg. No. 46,319
Telephone: (212) 588-0800
Facsimile: (212) 588-0500